

REMARKS

Claims 1, 2, 5, 6, 8, 10, 11, 14, 15, 17 and 23 are currently amended. It is respectfully submitted that the present amendments present no new matter and places this case in condition for allowance. Reconsideration of the application in view of the above amendments and the following remarks is requested.

I. The Rejection of Claims 1-23 under 35 U.S.C. 103(a)

Claims 1, 2, 4-6, 8, 10-11, 13-15, 17 and 19-23 are rejected under 35 U.S.C. 103(b) as being unpatentable over U.S. Patent No. 5,954,998 to Zhou (hereinafter referred to simply as "Zhou") in view of an article entitled *Polmersomes: Tough Vesicles Made of Diblock Copolymers* to Disher *et al.* (hereinafter referred to simply as "Disher") or vice versa (Disher in view of Zhou).

The present disclosure relates to enzymatic compositions including an enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle, and an encapsulation of enzyme in a uni-lamellar or multi-lamellar vesicle aspect is specifically recited in each independent claim.

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir.1991).

Zhou relates to a liquid peracid precursor composition for delivering a bleaching and cleaning material in which the liquid peracid precursor composition combines a dispersion medium which includes an amount of a liquid matrix and an emulsifier, and a dispersed phase that includes a peracid precursor. While Zhou may mention using preparations that contain enzyme and vesicles, Zhou is devoid of any suggestion or instruction on how to provide enzyme encapsulated in a vesicle. For example, at Column

16, the colloidal dispersions of Zhou may contain certain adjuncts, for example, *inter alia*, enzyme. However, there is no suggestion that the enzyme be encapsulated in a vesicle. Moreover, Zhou does not specifically teach the claimed enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle, wherein the vesicle includes at least 50% of a synthetic polymer as a vesicle forming agent; and wherein the synthetic polymer is a di- or tri-block-co-polymer composed of monomers selected from the group consisting of ethyleneoxide, propyleneoxide, ethylethylene, acrylic acid and vinyl amine.

Discher fails to cure the deficiencies of Zhou and *vice versa*. Specifically, Discher also fails to teach or suggest a method that employs encapsulating an enzyme in a uni-lamellar or multi-lamellar vesicle. More specifically, Discher is devoid of any suggestion to employ enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle. Rather, Discher relates to vesicles made from amphiphilic di block copolymers and characterized by micromanipulation.

Thus, nowhere do Zhou or Discher teach or suggest a composition including an enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle, wherein the vesicle comprises at least 50% of a synthetic polymer as a vesicle forming agent.

If one of skill in the art were to combine the teachings of Zhou and Discher (which Applicants do not concede is proper) the result would simply be to use the compositions of Zhou with the compositions of Discher or *vice versa*. Thus, one is just as likely to arrive at a combination of Zhou and Discher compositions having enzyme dispersed outside any vesicle than the Applicants claimed invention. Accordingly, nothing in any reference would teach suggest or motivate one skilled in the art to put enzyme inside the vesicle. As noted in the Applicants specification at page 1, line 19 "We have found the vesicles form from synthetic polymers can be used for encapsulation of compounds in order to protect the compounds from the chemical environment in which they are used." Further, on page 5, encapsulated compounds include enzymes. Moreover, Example I specifically teaches encapsulating an alpha-amylase enzyme in one or more vesicles. This encapsulation of enzyme aspect is specifically recited in each independent claim which require, *inter alia*, enzyme in the vesicle.

The only motivation offered by the Examiner to combine the polymersomes of Discher for encapsulating the enzymes of Zhou is that Discher allegedly teaches that the polymersomes have enhances toughness and reduced permeability of membranes and that each synthetic membrane *might* find its own application in transport, rheology or encapsulation, rationally based on a suitable selection of material properties, thermal behaviors and permeabilities. Applicants respectfully traverse the Examiner's position and submit that this is improper for the following reasons.

First, Applicants submit that the claimed invention is novel, *i.e.* not suggested in the prior art (*e.g.*: there are no remaining rejections under 35 U.S.C. 102). Where the prior art suggests that an area should be investigated, and yet the resulting invention is not suggested in the prior art, the claimed invention is not obvious. See for example, *In re Eli Lilly*, 902 F.2d, 943,945, 14 USPQ2d 1741, 1743 (Fed. Cir. 1990) ("An 'obvious-to-try' situation exists when a general disclosure may pique the scientist's curiosity, such that further investigation might be done as a result of the disclosure, but the disclosure itself does not contain a sufficient teaching of how to obtain the desired result, or that the claimed result would be obtained if certain directions were pursued.) The use of the word "might" suggests that Discher is limited to offering transport, rheology or encapsulation modifications as a field for future experimentation. Accordingly, the Examiner is using improper obvious to try rational and independent claims 1, 2, 5, 6, 8, 10, 11, 14, 15 and 17 are not obvious.

Second , although Discher does mention, *inter alia*, synthetic membrane might find its own application in transport, rheology or encapsulation, Discher is devoid of any indication of which parameters are critical to enable transport, rheology or encapsulation modifications to successfully encapsulate enzymes. Thus, Discher provides no direction as to which of the many possible choices are likely to be successful. Obvious-to-try rational is improper where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful. See generally *In re O'Farrell*, 853 F.2d 894, 903, 7 USPQ2d 1673, 1681 (Fed. Cir. 1988) (defining obvious-to-try as when prior art gives "only general guidance as to the particular form of the claimed invention or how to achieve it"). Accordingly, the Examiner is using improper obvious to try rational and independent claims 1, 2, 5, 6, 8, 10, 11, 14, 15 and 17 are not obvious.

Third, even assuming that the Examiner is correct in that compositions of Zhou could be used with the compositions of Discher (which Applicants do not concede would be proper), the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir.1990). See also, *In re Jones*, where the Court found there was no suggestion to combine the references to arrive at the claimed invention. Note, in this case no cited reference describes putting enzyme in the vesicle itself. Accordingly, independent claims 1, 2, 5, 6, 8, 10, 11, 14, 15 and 17 are not obvious.

In view of these facts, Applicants respectfully submit that there would be no motivation to modify the prior art (Zhou in view of Discher and *vice versa*) to incorporate enzyme in one or more vesicles. Independent claims 1, 2, 5, 6, 8, 10, 11, 14, 15 and 17 are not obvious and reconsideration is urged.

For the foregoing reasons, Applicants submit that the claims as amended overcome this rejection under 35 U.S.C. 103(b). Applicants respectfully request reconsideration and withdrawal of the rejection.

II. The Rejection of Claims 1-23 under 35 U.S.C. 103(b)

Claims 1-2, 4-6, 8, 10-11, 13-15, 17 and 19-23 are rejected under 35 U.S.C. 103(b) as being unpatentable over Zhou in view of Discher (or *vice versa*), further in view of WO 97/24177 (Hereinafter referred to simply as "Lykke"). This rejection is respectfully traversed.

As Applicants note, *supra*, Discher and Zhou do not provide motivation to modify the vesicles of Zhou and/or Discher to include enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle. Thus, the arguments above are herein incorporated by reference in their entirety to the extent that the Examiner has relied on the prior rejection of Discher and Zhou (and *vice versa*) in the present rejection.

Applicants also note that all independent claims have been amended to require a uni-lamellar or multi-lamellar vesicle. Reconsideration is urged in light of these amendments and the following remarks.

Lykke fails to cure the deficiencies of Zhou and Discher. Lykke fails to teach or suggest a composition or method that employs the enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle. For example, Lykke fails to teach enzyme encapsulated in a uni-lamellar or multi-lamellar vesicle including wherein the vesicle includes at least 50% of a synthetic polymer as a vesicle forming agent; and wherein the synthetic polymer is a di- or tri-block-co-polymer composed of monomers selected from the group consisting of ethyleneoxide, propyleneoxide, ethylethylene, acrylic acid and vinyl amine. Conversely, Lykke includes an encapsulation layer resulting from the coacervation or condensation reaction which is randomly cross-linked (i.e., web-like or plastic-like structure).

Lykke teaches away from the claimed invention. Lykke describes an encapsulation layer resulting from the coacervation or condensation reaction which is randomly cross-linked (i.e., web-like or plastic-like structure). Accordingly Lykke teaches away from using a uni-lamellar or multi-lamellar vesicle, one of ordinary skill in the art would not be motivated to modify the vesicles of Zhou and Discher with the vesicles of Lykke (and *vice versa*). Accordingly, independent claims 1, 2, 5, 6, 8, 10, 11, 14, 15 and 17 are not obvious.

Further, if one of skill in the art were to combine the teachings of Zhou, Discher, and Lykke (which Applicants do not concede is proper) the result would simply be to use the compositions of Zhou with the compositions of Discher and/or compositions of Lykke. Thus, one is just as likely to arrive at a combination of Zhou, Discher and Lykke compositions having enzyme dispersed outside any vesicle than the Applicants claimed invention. Accordingly, nothing in any references would teach suggest or motivate one skilled in the art to put enzyme inside a uni-lamellar or multi-lamellar vesicle.

Moreover, even assuming that the Examiner is correct in that vesicle of Zhou and Discher could be used with the compositions of Lykke (which Applicants do not concede would be proper), the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the

desirability of the combination. *In re Mills*, 916 F.2d 680, 16 USPQ2d 1430 (Fed. Cir.1990). See also, *In re Jones*, where the Court found there was no suggestion to combine the references to arrive at the claimed invention. Note, in this case no cited reference describes putting enzyme in a uni- or multi- lamellar structure itself.

In view of these facts, Applicants respectfully submit that there would be no motivation to modify the prior art (Zhou in view or Discher and/or Lykke) to incorporate enzyme in one or more uni- or multi- lamellar structures. Accordingly, independent claims 1, 2, 5, 6, 8, 10, 11, 14, 15 and 17 are not obvious.

For the foregoing reasons, Applicants submit that the claims as amended overcome this rejection under 35 U.S.C. 103. Applicants respectfully request reconsideration and withdrawal of the rejection.

III. Conclusion

In view of the above, it is respectfully submitted that all claims are in condition for allowance. Early action to that end is respectfully requested. The Examiner is hereby invited to contact the undersigned by telephone if there are any questions concerning this amendment or application.

Respectfully submitted,

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